

EXHIBIT 9

Additional questions from the review of Overview and the support documents
April 3, 2003
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Support Document # 2

1. The purpose section (p.1) describes one objective of the toxicity testing as allowing comparison of the toxicity information (of the active ingredient) with measured or estimated residues in the environment. Are toxicity tests of the metabolites or degradates routinely conducted? How can this comparison occur if the toxicity of the metabolites and degradates is unknown?
2. The approach section (p. 2) mentions that ASTM subcommittees are preparing standard practices for other studies such as aquatic accumulation. What is the status of that work? Please provide the background documentation for those standard practices, if they have been developed.
3. p. 27, Test substance (3). It appears that EPA has the authority to require toxicity testing of metabolite or degradates, end-use formulations, end-use formulations plus adjuvants or other vehicles, inerts and/or impurities of actives or inerts. Has any of this testing been conducted for diazinon? How often has this testing been required for new or reregistered pesticides? Have any metabolites, degradates, end-use formulations, end-use formulations plus adjuvants or other vehicles, inerts and/or impurities of actives or inerts of diazinon been tested? Please provide those data, if they exist.
4. p 78 and 81, (d) Acceptable protocols. Have the protocols for the fish early life-stage test, the invertebrate life-cycle, and or the life-cycle test for fish test been updated?
5. p. 78 and 80. Reporting and evaluation of data. How are the additional information such as locomotion, behavioral, physiological and pathological (6) incorporated into the ecological risk assessment? Please provide those data for diazinon.
6. p. 81. Aquatic organism accumulation tests. How often has this testing been required for new or reregistered pesticides? Please provide the data for diazinon, if the test has been conducted.
7. p. 83. Simulated or actual field testing for aquatic organisms. Have the background references for conducting the tests been updated? How often has this testing been required for new or reregistered pesticides? Please provide the data for diazinon, if the test has been conducted.

Support Document # 5

- 1 p. 23. F. Dissipation studies: combination products and tank mixes. The document states that EPA has data that indicate that the persistence of a pesticide in soil may increase as a result of its application with another pesticide serially or in a mixture. However, EPA only requires these data on a case-by-case basis. How often have these studies been required for new or reregistered pesticides? Please provide any mixture data for diazinon and other pesticides, inerts, adjuvants,

or surfactants, if the studies have been conducted.

2. p. 27. 3. Microecosystem studies. The document identified that study design criteria had not been developed. Have such designs been developed for employment in the pesticide chemical fate determinations? How often has this testing been required for new or reregistered pesticides? Please provide the data for diazinon, if the studies have been conducted.

3. p. 33. Table 1. It appears that fish accumulation testing is not required for domestic outdoor terrestrial uses, while that requirement does exist for non-crop, orchard crop, field and vegetable crop, and forestry uses. What is the rationale for not requiring fish accumulation data from domestic outdoor uses? Does this mean that there are no diazinon fish accumulation data from domestic uses? If there are data for domestic outdoor uses for diazinon, please provide them.

Support Document # 7

1. The discussion on pages 28-29 of the overview document appear to conflict. The guidance in support document # 7 provides guidance (p. 36) and offers a wide variety of questions to ask in order to select assessment endpoint (Text box 3-4, p. 29). The guidance states that "it is not necessary for methods to be standardized protocols, nor should assessment endpoints be selected simply because standardized protocols are readily available." How does the OPP process of solely considering standard reduced survival and reproductive impairment protocols comport with the need to capture a variety of ecosystem and population level effects?

Support Document # 10

1. This document states that the analysis of the most conservative region for a given crop has not been conducted as of February, 2002. Has this analysis been conducted as of present? What will be the basis for determining what is the most conservative region for a given crop? Are listed species/designated critical habitat built into the definition of "most conservative." Can listed species/designated critical habitat be built into that definition? How can exposure scenarios based in real space and time for ESA consideration be built into models?

It appears that developing new exposure scenarios can take between 2-4 days. NOAA Fisheries would like to work with EFED and the QA/QC Scenario Team to develop pilot scenarios for the diazinon and propargite consultations.

Support Document #22

1. Incident header. Is there any more specific information in the EGIS database on the location of the incident beyond the state and county?

2. Effect. How are other effects beyond mortality and acetylcholinesterase activity captured (i.e., behavioral, locomotion, physiological, etc) in the database?

3. Effect. How are life history stages (i.e., spawning, rearing, smoltification, migrating) captured

in the database?

4. Tissue. Are tissue samples taken solely from edible portion of a fish, or are the whole fish analyzed?

5. Environmental samples. Is water temperature measured made and captured in the database?

6. AI. Is the inert or adjuvants/surfactants recorded in the database?

7. Certainty. What is the basis for the level of certainty that exposure to a given pesticide(s) was the cause or contributor to the incident?

Support Document #29

1. What determines whether the technical grade of the active ingredient (TGAI), the pure active ingredient (PAIRA), end-use product (EP), or typical end-use product (TEP) is tested under the 40 CFR 158 requirements? How often is the formulated product subjected to acute or chronic testing? How often are simulated or actual field testing with aquatic organisms (§ 72-7) conducted?

2. To what do the guidelines reference numbers refer?

3. Why is there no EP or TEP testing required for aquatic organisms?

4. Footnote # 4 of 40 CFR 158.490 states that acute LC_{50} estuarine and marine organisms testing is required if "the product is expected to enter this environment in significant concentrations..." What is the definition of "significant"?

5. Footnote # 5 of 40 CFR 158.490 has a number of criteria, one of which must be met before fish early life stage and aquatic invertebrate life cycle tests are conducted. How can EPA reconcile the problem of the exposure modeling which is often invalidated by monitoring results, not triggering chronic/sublethal testing?

6. What is the rationale for limiting chronic/sublethal testing on the basis of the acute LC_{50} or EC_{50} ?

7. Footnote #7 of 40 CFR 158.490 identifies the estimated or maximum expected environmental concentration (MEEC) as the comparators for the technical grade acute LC_{50} or EC_{50} to trigger testing of the EP or TEP. How is the MEEC derived? How frequently is this trigger ever tripped?

This footnote also makes reference to synergist effects. What methods are used to trip this trigger? How frequently is this trigger ever tripped?

8. Presently, the nontarget insect data requirements do not have tests for aquatic insects (40 CFR 158.590). What is the status of the further evaluation that is noted in the regulations? Please

provide the background documentation for the outcome of the evaluation, if it has been developed.

9. Biochemical pesticides data requirements (40 CFR 158.69(d)). It appears that there is no chronic sublethal testing for biochemical pesticides. How does that gap satisfy EPA's data sufficiency requirements?